
21 U.S. Code § 355h

Regulation of certain nonprescription drugs that are marketed without an approved drug application

(a) Nonprescription drugs marketed without an approved application

Nonprescription drugs marketed without an approved drug application under section 355 of this title, as of March 27, 2020, shall be treated in accordance with this subsection.

(1) Drugs subject to a final monograph; category I drugs subject to a tentative final monograph

A drug is deemed to be generally recognized as safe and effective under section 321(p)(1) of this title, not a new drug under section 321(p) of this title, and not subject to section 353(b)(1) of this title, if—

(A) the drug is—

(i) in conformity with the requirements for nonprescription use of a final monograph issued under part 330 of title 21, Code of Federal Regulations (except as provided in paragraph (2)), the general requirements for nonprescription drugs, and conditions or requirements under subsections (b), (c), and (k); and

(ii) except as permitted by an order issued under subsection (b) or, in the case of a minor change in the drug, in conformity with an order issued under subsection (c), in a dosage form that, immediately prior to March 27, 2020, has been used to a material extent and for a material time under section 321(p)(2) of this title; or

(B) the drug is—

(i) classified in category I for safety and effectiveness under a tentative final monograph that is the most recently applicable proposal or determination issued under part 330 of title 21, Code of Federal Regulations;

(ii) in conformity with the proposed requirements for nonprescription use of such tentative final monograph, any applicable subsequent determination by the Secretary, the general requirements for nonprescription drugs, and conditions or requirements under subsections (b), (c), and (k); and

(iii) except as permitted by an order issued under subsection (b) or, in the case of a minor change in the drug, in conformity with an order issued under subsection (c), in a dosage form that, immediately prior to March 27, 2020, has been used to a material extent and for a material time under section 321(p)(2) of this title.

(2) Treatment of sunscreen drugs

With respect to sunscreen drugs subject to this section, the applicable requirements in terms of conformity with a final monograph, for purposes of paragraph (1)(A)(i), shall be the requirements specified in part 352 of title 21, Code of Federal Regulations, as published on May 21, 1999, beginning on page 27687 of volume 64 of the Federal Register, except that the applicable requirements governing effectiveness and labeling shall be those specified in section 201.327 of title 21, Code of Federal Regulations.

(3) Category III drugs subject to a tentative final monograph; category I drugs subject to

proposed monograph or advance notice of proposed rulemaking

A drug that is not described in paragraph (1), (2), or (4) is not required to be the subject of an application approved under section 355 of this title, and is not subject to section 353(b)(1) of this title, if—

(A) the drug is—

(i) classified in category III for safety or effectiveness in the preamble of a proposed rule establishing a tentative final monograph that is the most recently applicable proposal or determination for such drug issued under part 330 of title 21, Code of Federal Regulations;

(ii) in conformity with—

(I) the conditions of use, including indication and dosage strength, if any, described for such category III drug in such preamble or in an applicable subsequent proposed rule;

(II) the proposed requirements for drugs classified in such tentative final monograph in category I in the most recently proposed rule establishing requirements related to such tentative final monograph and in any final rule establishing requirements that are applicable to the drug; and

(III) the general requirements for nonprescription drugs and conditions or requirements under subsection (b) or (k); and

(iii) in a dosage form that, immediately prior to March 27, 2020, had been used to a material extent and for a material time under section 321(p)(2) of this title; or

(B) the drug is—

(i) classified in category I for safety and effectiveness under a proposed monograph or advance notice of proposed rulemaking that is the most recently applicable proposal or determination for such drug issued under part 330 of title 21, Code of Federal Regulations;

(ii) in conformity with the requirements for nonprescription use of such proposed monograph or advance notice of proposed rulemaking, any applicable subsequent determination by the Secretary, the general requirements for nonprescription drugs, and conditions or requirements under subsection (b) or (k); and

(iii) in a dosage form that, immediately prior to March 27, 2020, has been used to a material extent and for a material time under section 321(p)(2) of this title.

(4) Category II drugs deemed new drugs

A drug that is classified in category II for safety or effectiveness under a tentative final monograph or that is subject to a determination to be not generally recognized as safe and effective in a proposed rule that is the most recently applicable proposal issued under part 330 of title 21, Code of Federal Regulations, shall be deemed to be a new drug under section 321(p) of this title, misbranded under section 352(ee) of this title, and subject to the requirement for an approved new drug application under section 355 of this title beginning on the day that is 180 calendar days after March 27, 2020, unless, before such day, the Secretary determines that it is in the interest of public health to extend the period during which the drug may be marketed without such an approved new drug application.

(5) Drugs not GRASE deemed new drugs

A drug that the Secretary has determined not to be generally recognized as safe and effective under section 321(p)(1) of this title under a final determination issued under part 330 of title 21, Code of Federal Regulations, shall be deemed to be a new drug under section 321(p) of this title, misbranded under section 352(ee) of this title, and subject to the requirement for an approved new drug application under section 355 of this title.

(6) Other drugs deemed new drugs

Except as provided in subsection (m), a drug is deemed to be a new drug under section 321(p) of this title and misbranded under section 352(ee) of this title if the drug—

(A) is not subject to section 353(b)(1) of this title; and

(B) is not described in paragraph (1), (2), (3), (4), or (5), or subsection (b)(1)(B).

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